

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)
a Massachusetts Corporation)
Plaintiff,)
v.) Civil Action No. 04-12457 PBS
Arthrex, Inc.)
a Delaware Corporation, *et al.*)
Defendants.)

**DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S RESPONSE TO DEPUY
MITEK'S BENCH MEMORANDUM RELATING TO PRE-SUIT TESTING**

Dated: August 10, 2007

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Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

Defendants Arthrex, Inc. and Pearsalls, Ltd. (collectively "Arthrex") submit this paper in response to the bench memorandum relating to pre-suit testing filed by DePuy Mitek on August 3, 2007.

This Court has already stated the fact that DePuy Mitek conducted tests is not privileged information. Yet, DePuy Mitek continues to argue that Arthrex should not be permitted to refer to this *admissible* evidence, blithely contradicting this Court's prior pronouncement. As explained below, the fact that DePuy Mitek conducted tests is *not* privileged information. To the extent any question exists as to whether this information is privileged -- which there is none -- DePuy Mitek waived its claim of privilege. Further, DePuy Mitek's reliance on *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 434 F. Supp. 2d. 810 (E.D. Cal. 2006) is entirely misplaced. *McKesson* merely precludes evidence pertaining to the assertion of privilege, something Arthrex has already agreed not to introduce.

DePuy Mitek raised this issue in its second motion *in limine* and this Court responded that "it's not protected that you conducted tests, and that can come out." Ex. 1 at 27:23-24. The fact that DePuy Mitek conducted tests is *not* privileged information. Simply because DePuy Mitek believes "there will necessarily be an implicit adverse inference that the test results were unfavorable to Mitek" does not warrant the preclusion of otherwise *relevant and admissible* evidence. DePuy Mitek cites no law for the proposition that *relevant and admissible* evidence should be precluded simply because it is unfavorable to a party.

The fact that DePuy Mitek did tests, as this Court has repeatedly noted, is simply not privileged information. But even if DePuy Mitek had a colorable argument that the fact it conducted tests is privileged -- which they do not -- that argument was waived. DePuy Mitek has produced documents indicating that it conducted tests. Ex. 2 at 2d; Ex. 3 at 2b. DePuy

Mitek has likewise permitted testimony relating to these tests.¹ Ex. 4 at 58:6-59:2; 59:15-70:22.

DePuy Mitek cannot now claim that the fact that it conducted tests is privileged.

Furthermore, DePuy Mitek woefully overstates the facts and the holding of *McKesson*.² The *McKesson* court held that the plaintiff was “precluded, in all respects, from introducing evidence or testimony *pertaining to Bridge’s assertion of the attorney client privilege* over the opinion of counsel it received....” *Id.* at 812 (emphasis added). This Court has already stated that the results of the tests are likely privileged and instructed Arthrex’s Counsel not to argue the assertion of privilege to the jury. Ex. 1 at 28:6-13. *McKesson* does nothing more than restate the demarcation that this Court has already expressed.

For the foregoing reasons and the reasons in Arthrex’s response to DePuy Mitek’s motion *in limine* no. 2, Arthrex should not be precluded from submitting any evidence or making any argument to the jury about the existence of DePuy Mitek’s pre-suit testing.

¹ Such testimony regarding the pre-suit testing conducted by DePuy Mitek is the only remaining issue to be resolved on the deposition designation objections. Should the Court maintain its position that the fact that the tests were conducted is not privileged this remaining dispute should, likewise, be resolved.

² It is questionable if *McKesson*, a case regarding an opinion of counsel relating to patent infringement, even applies to this case where privilege is being asserted to protect the fact that tests were conducted.

Dated: August 10, 2007

Respectfully submitted,

By: /s/Charles W. Saber

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Arthrex, Inc. and Pearsalls Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S RESPONSE TO DEPUY MITEK'S BENCH MEMORANDUM RELATING TO PRE-SUIT TESTING was served, via the Court's email notification system on the following counsel for Plaintiff on the 10th day of August 2007:

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/s/Charles W. Saber

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC.,)
a Massachusetts Corporation,)
Plaintiff)
)
-VS-) CA No. 04-12457-PBS
) Pages 1 - 37
ARTHREX, INC.,)
a Delaware Corporation,)
and Pearsalls Ltd.,)
a Private Limited Company)
of the United Kingdom,)
Defendants)

FINAL PRETRIAL CONFERENCE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ.,
LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ.,
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2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891,
for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ.,
Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington,
D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
July 31, 2007, 4:00 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617) 345-6787

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1 privilege, as I understand it --

2 MR. SABER: Or work product, the same thing, your
3 Honor.

4 THE COURT: -- protection under the work product
5 doctrine. And it's just I don't know if it is or not. It's
6 quite clear that if a lawyer hires a private eye to go out
7 and take witness statements, that those are protected under
8 the work product doctrine, and you have to make certain
9 showings to get them. It's also clear you can't draw an
10 adverse inference if it's a fair application of a work
11 product doctrine. That's clear Federal Circuit law. Is this
12 the fair assertion of the work product doctrine? Have either
13 of you found a case on this?

14 MR. SABER: Yes, your Honor. I think we cited four
15 cases to you.

16 THE COURT: Not directly on this.

17 MR. SABER: Well, two of them were exactly on
18 point.

19 THE COURT: Which are the two that you say are
20 directly on point?

21 MR. SABER: I don't have the names, but they're the
22 first two that we cited, your Honor.

23 THE COURT: The first two?

24 MR. SABER: Yes.

25 THE COURT: Say what, that you can get what?

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1 MR. SABER: That there's no privilege for -- these
2 were both cases about test results done by the plaintiff in a
3 case.

4 THE COURT: Well, by the plaintiff, that's one
5 thing, but what if --

6 MR. SABER: That's what this is.

7 MS. VERRECCHIO: Your Honor, those tests were not
8 conducted at the request of counsel. And in this case,
9 in-house counsel for DePuy Mitek and outside litigation
10 counsel directed the tests to be done before the suit was
11 filed and in anticipation of litigation, so it's clearly work
12 product.

13 THE COURT: I'm just saying, we're two days before
14 trial. I don't know what the answer is. No one should argue
15 it in their opening. We did not find a case directly -- your
16 cases were not where they were directed by an attorney in
17 anticipation of litigation. On the other hand, we found a
18 case that said that the fact that there were tests was not
19 protected -- that's why it's not so straightforward -- the
20 fact that there are tests, but the results of the test may
21 well be protected. But, you know, just like an investigator
22 has to disclose whom he interviewed but maybe not what the
23 statement was. So I think it's not protected that you
24 conducted tests, and that can come out. But you can't ask
25 for an instruction on an adverse inference if in fact that

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1 they were protected or argue they should have been produced
2 because I think there's some argument that that is
3 protected. They're pretty fine lines that we're walking
4 here, and I am not prepared to rule right now, and no one
5 should argue any adverse inference in their opening
6 statements. You can argue that "You won't see any tests,"
7 because the absence of evidence is a strong thing in your
8 quiver because you do have tests, but that's different from
9 saying, "The lawyers ordered tests, and they won't produce
10 them," because I think there's at least a good shot that they
11 are protected, the actual results.

12 MR. SABER: Okay, well, I won't make that argument,
13 your Honor.

14 THE COURT: None of these want to be an appeal
15 issue. You don't want to draw -- unless you've got a slam
16 dunk about it, permitting an adverse inference on a test
17 conducted under the auspices of a lawyer in anticipation of
18 litigation are too close to the line, so we don't want that
19 appeal issue.

20 So then what are the other issues that we have?

21 MS. ELDERKIN: Your Honor, we had some issues come
22 up with Dr. Gitis' supplemental report. This was not raised
23 in the motions in limine because his deposition didn't happen
24 until last week. I'll let Mr. Bonella --

25 THE COURT: If it's not a motion in limine, I'm not

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1 dealing with it, okay. I have a room upstairs full. What
2 are the other motions in limine?

3 MR. TAMBURNO: Your Honor, we filed a motion in
4 limine on a new argument that DePuy Mitek made for the first
5 time late in this case regarding the minimal impact of
6 coating, and --

7 THE COURT: I read that, and that's overruled.
8 That's what their whole argument has been all along.

9 MR. TAMBURNO: Well, actually, it's not quite right,
10 your Honor. They've been arguing all along that the coating
11 does not prevent certain things from happening in the
12 suture. This is a new argument they're making, and they're
13 citing Dr. Brookstein to support it, but he never made these
14 arguments.

15 THE COURT: That's overruled. Yes, he did. I
16 mean, that was the whole gist of this thing, that it doesn't
17 matter, and it's just a tiny amount of coating, and it's
18 de minimis and insignificant. That's what this case is
19 about. Both of you are trying to get me to direct the case,
20 and I'm not going to do it.

21 What's the next motion in limine?

22 MS. MALINOSKI: We had filed a motion that was
23 directed to Arthrex trying to introduce evidence about the
24 development of the Orthocord product and the reasons that
25 Mitek developed it. Orthocord is a suture that DePuy Mitek

Exhibit 2

Katie's Current Projects 6/29/04

1. Project MoniTorr - CPC representative
 - a. Recently completed Design Verification completion reports for Cost Reduction project for Cartridge top and meatus cone changes.
 - b. Regularly attended weekly Cost Reduction meetings to keep up-to-date on progress.
 - c. One more cost reduction project in process (catheter change). Will likely require design verification testing.
 - d. Collaborated with Ziad Mohamed (cost reduction project leader), Sharon Shantz, and MoniTorr members from AVAIL medical.
2. Project Orthocord, Violet - CPC representative
 - a. Working with MITEK project leader, Jonathan Howe, to gather information for Marketing. White papers have been written by MITEK which included data gathered here in CPC.
 - b. Working with J/H and Dan Burkley to gather SEM pictures for MITEK marketing of violet Orthocord and competitor, Fiberwire.
 - c. Completed summary report memos of possible competitors to Orthocord, including MaxBraid and Arthrex Bio-Fastak and Corkscrew sutures.
 - d.

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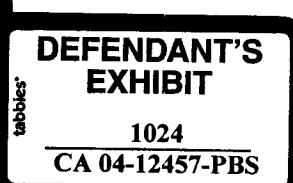
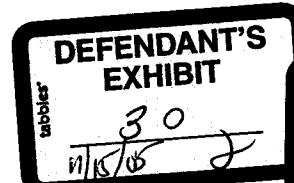
Coated and Uncoated Fiberwire was sent to test for straight tensile and bending rigidity as per a patent. Composition, SEM and denier analysis were needed to verify the coated and uncoated samples were the same. Bending rigidity was done in the patent using a Kawabata Bend tester. Tried to understand and learn how to use the tester in Ilya's lab.

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 PRODUCT PRIVILEGE

- e.
- f. Finalizing technical reports for violet ORTHCORD design verification and stability study.
- g. PQ is on-going in San Angelo.
- h. The second stability study for Orthocord violet is being developed. Les and I met to finalize the protocol. This protocol will test for 2X EO sterilization.
3. Project Orthocord, Blue - CPC representative
 - a. Spoke to Michael Pelekis to get ETHICON biocompatibility recommendations for Orthocord blue. MITEK has previous biocompatibility studies on D&C blue #6 for anchors. Michael and I are going to research biocompatibility studies for PDS blue. If enough information exists, it is ETHICON's recommendation that no new biocompatibility studies are needed.
 - b. Orthocord blue was brought to the stability study committee on 6/10/04. It was the stability committee's recommendation to initiate an off-critical path study to verify stability of the suture with the blue dye out to 5 years.
 - c. Currently working on revising the CPC Orthocord Blue plan. I would like to set up a CPC project review meeting soon.

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 DMI039571

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- d. Development samples of Orthocord blue are being made.
- e. Met with Enilma Miller to discuss using the violet TM's for blue. Most of them will not have to be updated. We would like to verify with the more development data.

4. LIMS

- a. Completed Agilent CSV 1st completion report. Qiang ran protocol a 2nd time successfully.
- b. The 2nd Agilent CSV completion report is written, awaiting signatures. The only items left are the SMP (which may need some testing) and the relevant SOPs.
- c. I have finalized the Waters SRS and have routed it for approval in ECCS.
- d. Waters IQ/OQ/PV was completed. Once I receive the paperwork, we can move into developing the tracematrix and any subsequent protocol and test scripts.
- e. Participated in Value Stream Mapping process with LIMS project team and Jim Pastore to create current state map of CPC processes.

5. Part 11/CSV

- a. I worked with Mark Storch to determine if there is any money in the R&D budget to bring in vendor to work on the remedial CSV of several pieces of equipment (including the Instron software, viscometer, titrator, NMR and x-ray Diffractometer.) Mark said there was capital money available. I worked with Mark and Darrie Christmas to determine if CSV would be capital or expense. With input from Phyllis Woodford and Jean Carbone, it was determined that it was.
- b. I have called Stelex to obtain a quote for the remedial CSV work on equipment previously mentioned. Currently working on putting together the information Stelex need to create their quote.
- c. I have worked with Robin Ragland and Josh Samon about obtaining quotes for software upgrades to the viscometer and x-ray Diffractometer. These upgrades would have to be done before the remedial CSV work. I spoke to the sales representative to the x-ray Diffractometer to clarify quote and have received new quote from Viscotek for the viscometer.
- d. I spoke to Jack Zhou about the Part 11/CSV plans. He felt the Instron Series IX software could be done in-house. For the x-ray Diffractometer, due to the time needed by the vendors to learn the equipment to do the CSV, it may take less time for Josh to do the CSV himself, then to spend time teaching the vendors about the equipment. I need to talk to Josh about this issue. Jack Zhou has also obtained a quote from Nugenesis for them to perform the CSV – not to be done in-house.
- e. I attended a conference call with Part 11 leaders in the field concerning new issues around Part 11.

6. Barbed Suture

- a. There are no new updates on the Belle project.

7. Calibration

- a. Still trying to get onto the Pilgrim system. There have been many software related problems with my access. I have been working with Pat Raics to gain access.
- b. Once I get on the system, inventory of all the equipment in CPC can roll out.

- c. Analytical chemistry has already begun their inventory with help from Robin Larkin and May Xu.
- 8. Mulberry
 - a. Samples will be here this week to start stability study. I will be working with Claudia to complete the baseline testing.

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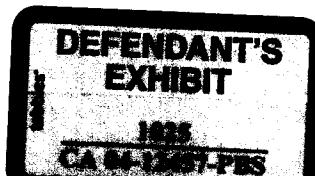
Exhibit 3

Katie's Current Projects 7/26/04

1. Project MoniTorr – CPC representative
 - a. Regularly attended weekly Cost Reduction meetings to keep up-to-date on progress.
 - b. Met to discuss requirement matrix for 3rd cost reduction project – catheter change. Design Verification testing including CMG flow rate, pressure accuracy, catheter diameter, catheter length and tube length will need to be done.
 - c. Started this Design Verification Protocol
 - d. Collaborated with Hannah Davies (cost reduction project leader), Sharon Shantz, and MoniTorr members from AVAIL medical.
2. Project Orthocord, Violet - CPC representative
 - a. Working with MITEK project leader, Jonathan Howe, to gather information for Marketing. White papers have been written by MITEK which included data gathered here in CPC.
 - b. *REDACTED DUE TO
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PRODUCT PRIVILEGE*

Tested coated and uncoated Fiberwire for straight tensile and bending stiffness. Mitek would now like to remove the coating from finished goods Fiberwire and test again.

 - c. Finalized technical reports for violet ORTHCORD design verification, stability study and other studies.
 - d. Orthocord violet launched for non-needled product. Investigation is on-going for needled product failure in OQ.
 - e. The second stability study for Orthocord violet is being developed. Should sing off on the protocol this week. This protocol will test for 2X EO sterilization.
3. Project Orthocord, Blue – CPC representative
 - a. CPC project review meeting set up for next week.
 - b. Development/Coating samples in sterilization. I should have them today.
 - c. Met with Enilma Miller, Ilya Koifman, Don Hill to discuss Orthocord blue development testing plan.
4. LIMS
 - a. Waters SRS approved in ECCS.
 - b. Started Waters traceability matrix.
 - c. Started the Instron Series IX SRS.
 - d. Met with several CPC associates (Christophe, Liz, Chris, Hwason, Debi) to explain and discuss filling out data gathering survey for LIMS.
 - e. Filled out survey.
5. Part 11/CSV
 - a. Worked with Stelex to put together quote for remedial CSV. Put together CAR for the work. Awaiting response.
 - b. I have obtained software upgrade quotes for x-ray Diffractometer and Viscometer. I am going to meet with Jack to put in PO's. Once they complete the upgrades, Stelex can come in and start the CSV.

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- c. I attended John Sheets' staff meeting to give an update on Part 11. JS wanted assessments done of all of R&D. I am going to coordinate this assessment. Meeting with Mark and Jack this Friday to discuss.
- d. Attended a meeting with Kathye Concannon, Robin Larkin, Rich Hutchinson, Len Chiu concerning a Honeywell monitoring system they might purchase for LAR.
- 6. Barbed Suture
 - a. Belle is now the Barbed suture project. Met with Nick Popadiuk to test a few in-house produced samples.
 - b. Met with Nick, Brian Lisa and others to discuss the relationship matrix.
- 7. Calibration
 - a. Started the inventory listing. I put together the lists that the Calibration dept. has of CPC equipment and sent out to the group. I have asked that everyone do any inventory and get back to me.
 - b. I will be compiling the lists and setting up meetings to discuss new equipment.
- 8. Mulberry
 - a. Completed baseline stability study testing with Claudia on TVT-O.

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DMI039561

Exhibit 4

30(b)(6) Deposition of
Katherine Seppa

February 10, 2006

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TRAVEL TRANSCRIPT

DePUY MITEK, INC.,
A Massachusetts Corporation,
Plaintiff,
v.
ARTHREX INC.,
A Delaware Corporation,
Defendants.

30(b)(6) DEPOSITION OF KATHERINE SEPPA
Somerset, New Jersey
February 10, 2006

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO.: SE 226

